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Reforming the countermeasures injury compensation program for COVID-19 and beyond: An economic perspective

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ABSTRACT

As of Aug. 2, 2021, 1693 injury claims associated with COVID-19 medical countermeasures have been filed in the Countermeasures Injury Compensation Program (CICP), of which 686 claims were related to COVID-19 vaccines and urgently needed compensation decisions. However, from an economic and public policy perspective, we find that the CICP design has unintended consequences: locating CICP in the executive agency DHHS

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potentially creates a conflict of interest, and not permitting judicial review generates a lack of checks and balances, both of which could jeopardize justice. These fundamental problems would subsequently weaken four key performance indicators of CICP compared with its judicial counterpart in the Court of Federal Claims. CICP lacks accountability, transparency, and cost-effectiveness efficiency, with 94% of its total costs spent on administration rather than compensation. CICP's ability to compensate is also questionable. If COVID-19 claims were compensated at its historical rate, CICP would face around $21.16 million in compensation outlays and $317.94 million in total outlays, 72.1 times its current balance. To ensure just compensation for injured petitioners during COVID-19 and future public health emergencies, we recommend Congress (1) initiate a major reform by relocating CICP from DHHS to the Claims Court or (2) keep CICP within DHHS and make incremental changes by permitting judicial review of DHHS administrative adjudication of CICP claims. We further recommend Congress audit and adjust budgets for CICP and DHHS promptly propose an injury table for COVID-19 claims. This is the first study that contributes an economic perspective to the limited literature on CICP and also provides unique and rich economic data.

KEYWORDS: Ability to Compensate, Accountability and Transparency, Administrative Costs, Cost-effectiveness Efficiency, COVID-19 Vaccine Injury Compensation, Just Compensation

I. THE COUNTERMEASURES INJURY COMPENSATION PROGRAM

As of Aug. 2, 2021, the COVID-19 pandemic in the U.S. has caused 35.5 million confirmed cases and 612 thousand deaths.[1] To combat the pandemic, the U.S. Food and Drug Administration (FDA) granted emergency approval of three novel vaccines produced by Biotech-Pfizer, Moderna, and Johnson & Johnson to immunize 70–90% of the total population.[2] To date, although 192.2 million (58% of total population) Americans have received at least one dose of these vaccines, the elderly and children have higher vaccination rates, including 90% at 65 years or older, 70% at 18 years or older, and 68% at 12 years or older. Furthermore, 165.4 million (50% of total population) are fully vaccinated, including 80%, 61%, and 58% at 65, 18, and 12 years or older, respectively.[3] However, although rare, 1693 injury claims associated with COVID-19 medical countermeasures (ie vaccines, antiviral drugs), with injuries ranging from anaphylaxis to death,[4] have been filed in the federal Countermeasures Injury Compensation Program (CICP), of which 686 claims were specifically related to COVID-19 vaccines.[5] These injuries may contribute to vaccine hesitancy among members of society and present an urgent need to compensate injured individuals.

1 U.S. Centers for Disease Control and Prevention, *COVID Data Tracker*, https://covid.cdc.gov/covid-data-tracker/#datatracker-home (accessed Aug. 2, 2021).

2 Kevin G. Volpp, Carolyn C. Cannuscio, *Incentives for Immunity—Strategies for Increasing COVID-19 Vaccine Uptake*, 385 N Engl J Med (2021).

3 *Supra* note 1.

4 U.S. Centers for Disease Control and Prevention, *Selected Adverse Events Reported after COVID-19 Vaccination*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html (accessed Aug. 2, 2021).

5 U.S. Health Resources and Services Administration, *Countermeasures Injury Compensation Program (CICP) Data*, https://www.hrsa.gov/cicp/cicp-data (accessed Aug. 2, 2021).

The CICP, established as part of the Public Readiness and Emergency Preparedness (PREP) Act of 2005,[6] serves as a liability shield for manufacturers, distributors, and administers of countermeasures deemed critical to the response and prevention of a declared public health emergency, providing a public liability insurance mechanism to compensate for injuries caused by such countermeasures.[7] The CICP is financed by general taxes held in the Covered Countermeasure(s) Process Fund (CCPF) through Congressional appropriations,[8] is located in the Department of Health and Human Services (DHHS), and is operated by the Health Resources and Services Administration (HRSA).[9] The CICP "provide[s] medical and lost employment income benefits to certain individuals [petitioners hereafter] who sustained a covered injury as the direct result of [a.k.a., causality criteria] the administration or use of a covered countermeasure."[10] Compensation decisions are determined using petitioners' medical records, and an injury table listing injuries caused by each particular covered countermeasure.[11] Injuries not listed on the table may also be compensated if petitioners can provide "compelling, reliable, valid, medical and scientific evidence of causality."[12]

However, none of the existing injury tables are applicable for COVID-19 countermeasures, and to date no new table, particularly for COVID-19 countermeasures, has been announced to meet the needs of existing and forthcoming COVID-19 claims in the CICP,[13] which may signal a lack of efficiency. The CICP also historically lacks transparency and accountability due to its location in the executive agency DHHS, which has a conflict of interest problem (see Section III). Moreover, the CICP has a questionable ability to compensate, suggesting mechanism design problems. Some of the weaknesses in CICP performance have been reported and policy recommendations have been proposed from a legal perspective.[14] However, to the best of our knowledge, other weaknesses have not been analyzed and corresponding policies not proposed from an economic perspective.

After searching the literature on CICP using the terms "Countermeasures Injury Compensation Program," "CICP," or "Covered Countermeasure(s) Process", we found

6 Public Readiness and Emergency Preparedness Act of 2005, Pub L. No. 109–148 (2005); Teneille R Brown, *When the wrong people are immune*, 7 J Law Biosci lsaa018 (2020).

7 U.S. Department of Health and Human Services, *Countermeasures Injury Compensation Program (CICP): Administrative Implementation Final Rule—76 FR 62306*, https://www.federalregister.gov/documents/2011/10/07/2011-25858/countermeasures-injury-compensation-program-cicp-administrative-implementation-final-rule (accessed Aug. 2, 2021).

8 U.S. Department of the Treasury, *Covered Countermeasure Process Fund Federal Account Profile*, https://www.usaspending.gov/federal_account/075-0343 (accessed Sept. 1, 2021).

9 *Supra* note 7; Lloyd Dixon, Kenneth R. Feinberg, Nicholas M. Pace, Paul Rheingold. *COVID-19 Vaccine Liability and Compensation in the United States*, https://www.rand.org/pubs/presentations/PTA1138-2.html (accessed Aug. 2, 2021).

10 *Supra* note 7.

11 U.S. Department of Health and Human Services, *Countermeasures Injury Compensation Program: Pandemic Influenza Countermeasures Injury Table*, https://www.govinfo.gov/content/pkg/CFR-2016-title42-vol1/xml/CFR-2016-title42-vol1-part110-subpartK.xml(accessed Aug. 2, 2021).

12 *Supra* note 7.

13 U.S. Health Resources and Services Administration, *Supra* note 5; Health Resources and Services Administration, *Freedom of Information Act (FOIA) Request Case Number 21F222*, (2021).

14 Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 Adm Law Rev 785 (2011); Peter H. Meyers, *The Trump Administration's Flawed Decision on Coronavirus Vaccine Injury Compensation: Recommendations for Changes*, 7 J Law Biosci lsaa082 (2020); Dixon et al., *Supra* note 9.

only a few articles. Two of these articles, published before 2010, provide preliminary reviews of the program. Gostin (2006) and Taylor (2010) acknowledge the need for liability protection and compensation mechanism that respectively protects manufacturers and compensates the injured,[15] but at the same time question assigning liability determination to DHHS, as a political figure, as a result of overstated negative effect of legal liability on the pharmaceutical industry. Mello (2008) compares CICP to the alternative federal Vaccine Injury Compensation Program (VICP), which covers routinely administered vaccines in non-emergency situations and also uses injury tables, and criticizes CICP, which does not allow injured petitioners to file claims in VICP, revealing the inconsistency in the American approach to vaccine injury compensation policy.[16] Apolinsky and Van Detta (2010) criticize the limited justice in compensation offered by CICP, whereas Parmet (2010) similarly criticizes the justice in its decision making, noting a general lack of protection for the public.[17] Holland (2018) highlights many issues with CICP and the liability protection offered under the PREP Act, questioning its constitutionality.[18] Parasidis (2017) further urges the need for modernizing vaccine injury compensation in the U.S.[19] Two articles from Meyers address some CICP issues more comprehensively.[20] Meyer (2011) discusses Congressional intent that both CICP and VICP induce countermeasure production and provide non-adversarial compensation, but criticizes CICP's lack of transparency and restrictive provision of compensation. Meyer (2020) further highlights the possible impact of these shortcomings in the context of the COVID-19 pandemic and compares CICP with VICP, which provides more petitioner participation, publishes its decisions, and allows judicial review. Based on arguments from the legal perspective, Meyer (2020) recommends reforming the program by lowering the legal standard of proof, permitting judicial review, and ensuring adequate funds. RAND Corporation also compares CICP with VICP and echoes many of the same criticisms.[21] However, none of this limited literature addresses CICP (1) design problems, such as DHHS potential conflict of interest and lack of checks and balances through a judicial review and (2) subsequent economic performance issues, such as efficiency and ability-to-compensate.

This article is the first to study CICP using the economic perspective and rich economic data. Part II reviews the historical development of CICP and congressional intent in its design. Parts III–VI evaluate each of the four CICP performance indicators: accountability, transparency, efficiency, and ability to compensate. In each Part, we also compare CICP, located in the executive branch, with its counterpart VICP, located

15 Lawrence O. Gostin, *Medical Countermeasures for Pandemic Influenza: Ethics and the Law*, 295 JAMA 554 (2006); Paul Taylor, *We're All in This Together: Extending Sovereign Immunity to Encourage Private Parties toReduce Public Risk*, 75 U. Cin. L. Rev. 1595, 1633–34, 1643–46 (2007).

16 Michelle M. Mello, *Rationalizing Vaccine Injury Compensation*, 22 Bioethics 1 (2008).

17 Joanna B. Apolinsky & Jeffrey A. Van Detta, *Rethinking Liability for Vaccine Injury*, 19 Cornell J. L. Pub. Pol 537, 561 (2010); Wendy E. Parmet, *Pandemics, Populism and the Role of Law in the H1N1 Vaccine Campaign*, 4 St Louis U. J. Health L. Pol 113, 146 (2010) at 152

18 Mary S. Holland, *Liability For Vaccine Injury: The United States, the European Union, and the Developing World*, 67 Emory L. J. 415, 450 (2018).

19 Efthimios Parasidis, *Recalibrating Vaccination Laws*, 97 Bost.U. L. Rev. 2153, 2236 (2017).

20 Meyers (2011), *Supra* note 14; *Meyers (2020), Supra* note 14.

21 Dixon et al., *Supra* note 9; Nicholas M. Pace & Lloyd Dixon, *COVID-19 Vaccinations: Liability and Compensation Considerations Critical for a Successful Campaign*, RAND Corporation (2020).

in the judicial branch (Table 1). Part VII summarizes the overall performance of CICP and discusses potential counterarguments that may justify some weaknesses in its performance. To resolve weaknesses, Part VIII recommends a major reform and incremental changes for Congress and DHHS to improve CICP. Part IX concludes.

II. HISTORICAL DEVELOPMENT OF CICP

In the context of national threats, including the September 11th terrorist attack in 2001, anthrax threats in 2001, and Severe Acute Respiratory Syndrome outbreak in 2003,[22] the avian flu H5N1 outbreak in 2004 directly triggered the creation of the PREP Act and the CICP in it.[23] The design of CICP was debated under the PREP Act of 2005, which was passed as an attachment to an important defense spending bill.[24] Proponents of the Act argued that liability protection was necessary to induce rapid production of life-saving countermeasures.[25] However, opponents, such as Senator Edward Kennedy, saw the liability immunity as overly protective of pharmaceutical manufacturers and the compensation program as exceedingly vague for injured individuals.[26] As a result of attaching it to the defense spending bill, the PREP Act was easier to pass with 308:106 votes in the House and 93:0 votes in the Senate,[27] and was signed into law by President George W. Bush. After searching all Congressional hearings and documents, we found no legislative proposals that amend the CICP subsection of the PREP Act of 2005.[28]

Moreover, we found no specific language regarding why Congress located CICP in the executive branch, rather than the judicial branch, and designated DHHS to implement it. Anecdotal evidence reveals that legislators have an overall assumption that executive agency actions are faster than judicial decisions.[29] Working on this assumption and recognizing the authority of DHHS to declare public health emergencies, it seems natural that Congress located CICP in DHHS for implementation.

Furthermore, we found no specific language regarding why Congress did not permit judicial review of DHHS agency actions on CICP claims. Anecdotal evidence suggests that the costs of traditional court decisions are relatively time-consuming and expensive. Despite the assumptions that DHHS would be more efficient, it took > 5

22 Homeland Security Council, *National Strategy for Pandemic Influenza*, https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-strategy-2005.pdf (Accessed Dec. 20, 2021); Sarah A. Lister, *Pandemic Influenza: Domestic Preparedness Efforts*, https://biotech.law.lsu.edu/cases/vaccines/RL33145.pdf (Accessed Dec. 20, 2021).

23 Gostin (2006), *Supra* note 15.

24 Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, Pub. L. No. 109–148 (2005).

25 Center for Infectious Disease Research and Policy, *Pandemic funding, liability shield clear congress*, https://www.cidrap.umn.edu/news-perspective/2005/12/pandemic-funding-liability-shield-clear-congress (Accessed Dec. 20, 2021); U.S. Senate, Crossing the Valley of Death: Bringing Promising Medical Countermeasures to Bioshield, Senate Hearing 109–148 (2005).

26 Centers for Infectious Disease Research and Policy (2005), *Supra* note 25.

27 U.S. House of Representatives, Final Vote Results for Roll Call 669, https://clerk.house.gov/evs/2005/roll669.xml (Accessed Dec. 20, 2021); U.S. Senate, Roll Call Vote 109th Congress—1st Session, https://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=109&session=1&vote=00366 (Accessed Dec. 20, 2021); U.S. Senate, Roll Call Vote 109th Congress—1st Session, https://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=109&session=1&vote=00366 (Accessed Dec. 20, 2021).

28 U.S. Government Publishing Office, GovInfo.gov, https://www.govinfo.gov/ (accessed Dec. 23, 2021).

29 Dixon et al, *Supra* note 9.

Table 1. Comparing CICP and VICP: Issues from an economic perspective

Issues	CICP	VICP
Location	Administrative system (DHHS-HRSA), governed by administrative law, lacks a tradition of precedential value, does not make precedents available, and may shield CICP adjudicators from being questioned by petitioners.	Judicial system (the Claims Court), governed by judicial law, has authority to issue judicial adjudication for individual cases, follows a case law tradition valuing precedents, and is required by judicial law to explain the reasoning for its judgements.
Transparency	No. CICP decision-makers, decision-making processes, and compensation details are publicly unavailable.	Yes. VICP decision-makers, decision-making processes, and compensation details are publicly available.
Accountability	No. DHHS serves as both the adjudicator and defendant, resulting in conflict of interest.	Yes. DHHS serves as the defendant only, whereas the Claims Court is the adjudicator.
Independent third-party adjudicator	Unclear. Although "Administrator of the HRSA" is assigned to manage the program. No natural person is held accountable for any unjust decision.	Yes. Special masters and judges with legal qualifications and vaccine case specialization hold initial case reviews and subsequent hearings, and provide reasons for claim decisions.
Reconsideration/ appeal processes	CICP petitioners can request one-step administrative reconsideration conducted by an 'independent panel' whose identities and qualifications are unknown, and judicial appeals are not permitted.	VICP petitioners are allowed to appeal to the US Courts of Appeals, which have multi-judge panels to provide more just and accountable adjudication.

Continued

Table 1. Continued

Issues	CICP	VICP
Cost-effectiveness efficiency	Questionable.	Yes.
Administrative costs	High. Of the $9.21 million spent by CCPF during FY 2017–2021, $8.64 million (94%) was spent on administrative costs, 15.03 times the $0.57 million (6%) spent on compensation. On a per capita basis, during FY 2010–2021, CICP average administrative cost per adjudicated claim is $41,892, and average compensation per adjudicated claim is $45,697.	Low. Of the $1.26 billion spent by VITF during FY 2017–2021, only $145.71 million (12%) were spent on administrative costs, leaving the majority $1.1 billion (88%) on compensation. On a per capita basis, during FY 2010–2021, VICP average administrative cost per claim is $24,719, and average compensation per claim is $243,129.
Time costs	No statutory time limits. COVID-19 countermeasures injury claims were not adjudicated as of May 14, 2021; two claims were adjudicated as of Aug. 2, 2021. Rough processing time of a COVID-19 claim in CICP ranges 7.5–17 months (225–510 days).	Low. Statutory time limits of 240 and 420 days, respectively, for a special master opinion and a Court final judgement.
Ability to compensate	Questionable. Assuming current COVID-19 claims were to be compensated at the historical rate, without accounting for future claims after Aug. 2, 2021, the program would face about $21.16 million in compensation outlays, 4.8 times its current balance of $4.41 million, and face about $317.94 million in total outlays, 72.1 times its current balance, if administrative costs were added to these compensations also at the historical rate.	Yes.

Notes: DHHS: Department of Health and Human Services; HRSA: Health Resources and Services Administration. Claims Court is the U.S. Court of Federal Claims; CCPF: covered countermeasure process fund; VITF: vaccine injury compensation trust fund. *Source*: Results are prepared by authors using references: *Supra* note 7; *Supra* note 8; Meyers (2020) *Supra* note 14; *Supra* note 25; *Supra* note 35; U.S. Court of Federal Claims, *Supra* note 50; U.S. Federal Rules of Civil Procedure, *Supra* note 50.

years to issue the Final Rule of implementing CICP.[30] Since then, criticisms of DHHS have alleged overly secretive and restrictive compensation and an unfair lack of judicial review.[31]

We analyze how these designs lead to unintended consequences: (1) locating CICP in DHHS creates a potential conflict of interest and (2) not permitting judicial review generates a lack of checks and balances. Subsequently, these unintended but fundamental problems could produce further weaknesses in four key performance indicators: (a) accountability, (b) transparency, (c) cost-effectiveness efficiency, and (d) ability to compensate.

III. ACCOUNTABILITY OF CICP

The lack of accountability for its decisions is a significant shortcoming of the CICP. First, DHHS has a potential conflict of interest to implement CICP: Although DHHS represents the U.S. federal government in both programs, it serves solely as the defendant in VICP, whereas the Claims Court is the adjudicator.[32] However, DHHS serves both roles in CICP.[33] As the defendant, the DHHS has fewer funds left if CICP, under its implementation, incurs more expenses. Acting as the adjudicator, if DHHS declines a CICP claim, it reduces these expenses. Thus, DHHS has more incentive to decline a claim and less incentive to decide in favor of the petitioner. This creates a potential conflict of interest problem for DHHS.

The DHHS potential conflict of interest coincides with the observation that the CICP's compensation rate, which is 6%,[34] is significantly lower than that of VICP's rate, which is 33–40% (Table 2).[35] Admittedly, CICP adjudicates injuries associated with emergency countermeasures that may not have accumulated enough evidence of causality for compensation, which can partially explain its low rate. However, this may also result from the DHHS inherent conflict of interest, which could then jeopardize justice.

Second, the DHHS's final rule of implementing CICP vaguely assigns the 'Administrator of the HRSA' to manage the program,[36] but does not specify natural persons to be responsible for CICP adjudication and does not allow petitioners to interact with adjudicators.[37] Consequently, no natural person can be held accountable for any unjust decisions. In contrast, the VICP judicial process uses independent third-party adjudicators: to each claim, the Claims Court appoints a "special master" with legal qualifications to do initial reviews, hold hearings with petitioners, and provide reason-

30 *Supra* note 7; Meave P. Carey, *The Federal Rulemaking Process: An Overview*, Congressional Research Service (2013), http://sgp.fas.org/crs/misc/RL32240.pdf (accessed Dec. 23, 2021).

31 Meyers (2011), *Supra* note 14; Meyers (2020), *Supra* note 14.

32 Molly T. Johnson, Carol E. Drew, & Dean P. Miletich. Use of Expert Testimony, Specialized Decision Makers, and Case-Management Innovations in the National Vaccine Injury Compensation Program (1998).

33 *Supra* note 7.

34 *Supra* note 5.

35 U.S. Health Resources and Services Administration, *Vaccine Injury Compensation Data*, https://www.hrsa.gov/vaccine-compensation/data/index.html (accessed Aug. 2, 2021).

36 *Supra* note 7.

37 Meyers (2020), *Supra* note 14.

Table 2. Comparing CICP and VICP: Claims

Countermeasure or vaccine	Alleged injury	Number of claims Filed	Number of claims compensated	Number of claims unentitled or Denied	Number of claims unadjudicated
CICP Claims: Fiscal Years 2010–2021 As of Aug. 2, 2021					
Related to COVID-19					
COVID-19 vaccines*	Deep vein thrombosis, heart attack, death, etc.	686	0	1	685
Countermeasures including COVID-19 test	Brain injury, perforated ethmoidal artery, death, etc.	4	0	0	4
Countermeasures including ventilator	Collapsed lung, respiratory failure, death, etc.	474	0	1	473
Other COVID-19 Countermeasures (eg antiviral drugs)	Renal failure, pulmonary embolism, death, etc.	529	0	0	529
Total		**1693**	**0**	**2**	**1691**
Unrelated to COVID-19					
H1N1 Vaccine	Guillain-Barrè Syndrome, bursitis, anaphylaxis, etc.	410	29	374	0
Total		**410**	**29**	**374**	**0**

Continued

Table 2. Continued

Countermeasure or vaccine	Alleged injury	Number of claims Filed	Number of claims compensated	Number of claims unentitled or Denied	Number of claims unadjudicated
Selected VICP Claims: Calendar Year 2006–2019					
DTP vaccines	N/A	1123	769	354	N/A
HPV vaccines	N/A	371	146	225	N/A
Seasonal influenza vaccines	N/A	5000	4260	740	N/A
MMR vaccines	N/A	266	132	134	N/A
Pneumococcal conjugate vaccines	N/A	158	98	60	N/A
All VICP Claims Total		**8395**	**5951**	**2444**	**N/A**

Notes: * COVID-19 vaccine product name is not specified by source. DTP: diphtheria, tetanus, and pertussis; HPV: human papillomavirus; MMR: measles, mumps, and rubella. N/A indicates information unavailable. *Source*: Data are retrieved from references *Supra* note 5; *Supra* note 35.

ing and opinion for or against the entitlement of and compensation for each claim.[38] The Claims Court further appoints a judge to review the special master's opinion and confer the final judgment, both of whom are specialized in vaccine injury claims.[39] At the outset, each petitioner knows which particular special master is assigned to and responsible for the claim, establishing accountability.[40]

Third, in case of disputes, CICP only allows for a one-step administrative reconsideration conducted by an "independent panel" and does not permit judicial appeals.[41] "No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary [of DHHS] under this [judicial review] subsection," according to the PREP Act of 2005.[42] Instead, the panel consists of "qualified individuals who are independent of the program," but their identities and qualifications relevant to adjudicating injury claims are not specified.[43] In contrast, VICP petitioners are allowed to appeal to the U.S. Courts of Appeals (or Appeals Court), whose multi-judge panels can provide more just and accountable decisions.[44] Therefore, without judicial review of DHHS executive agency actions on CICP claims, CICP lacks checks and balances, and thus lacks accountability.

IV. TRANSPARENCY OF CICP

The lack of transparency in the entire decision process is another obvious shortcoming in CICP implementation and has causes rooted in its location in the DHHS. Although the CICP publishes the total numbers of historical claims filed and compensated,[45] their contents, decision-makers, decision-making processes, and compensation details are not publicly available.[46] In contrast, the VICP makes all this information publicly available.[47] Such a gap in transparency results from differences between the administrative and judicial systems to which the two programs belong.

First, the VICP (or Vaccine Court),[48] as part of the National Childhood Vaccine Injury Act (NCVIA) of 1986,[49] is located in the U.S. Court of Federal Claims (or Claims Court) to issue judicial adjudication for individual vaccine injury cases and is

38 U.S. Court of Federal Claims, *Vaccine Claims/Office of Special Masters*, https://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters (accessed Aug. 2 2021); Johnson et al, *Supra* note 32.

39 *Id.*

40 *Supra* note 32.

41 *Supra* note 7.

42 PREP Act, *Supra* note 6.

43 *Supra* note 7.

44 Johnson et al, *Supra* note 32.

45 *Supra* note 5.

46 Meyers (2011), *Supra* note 14; Meyers (2020), *Supra* note 14; Katherine Van Tassel, Cermel Sachar, Sharona Hoffman, *Covid-19 Vaccine Injuries—Preventing Inequities in Compensation*, 384 N Engl J Med e34 (2021); Lawrence O. Gostin, *Medical Countermeasures for Pandemic Influenza: Ethics and the Law*, 295 JAMA 554 (2006); H. Cody Meissner, *A Viral Pandemic, Vaccine Safety, and Compensation for Adverse Events*, 325 JAMA 721 (2021); Yasuhiro Fujiwara, Yutaka Onda, Shuichiro Hayashi, *No-Fault compensation schemes for COVID-19 medical products*, 397 Lancet 1707 (2021)

47 Meyers (2011), *Supra* note 14.

48 We use VICP and Vaccine Court interchangeably throughout the article. When comparing to CICP, we use VICP; when discussing policies, we use Vaccine Court.

49 U.S. Health Resources and Services Administration, *About the National Vaccine Injury Compensation Program*, https://www.hrsa.gov/vaccine-compensation/about/index.html (accessed Aug. 2, 2021).

Table 3. Comparing CCPF and VITF: Spending categories FY 2010–2021 ($ USD)

	CCPF				VITF						
FY	Claims comp.	Claims comp. deflated (2021$)	Admin. costs on HRSA	Admin. costs on HRSA deflated (2021$)	Claims comp.	Claims comp. deflated (2021$)	Admin. costs on DOJ	Admin. costs on HRSA	Admin. costs on CFCP	Admin. costs on 3 Agencies	Admin. costs on 3 agencies deflated (2021$)
2010	N/A	N/A	N/A	N/A	188,000,000	235,000,000	8,000,000	7,000,000	5,000,000	20,000,000	25,000,000
2011	N/A	N/A	3,000,000	3,630,000	231,000,000	279,510,000	6,000,000	6,000,000	5,000,000	17,000,000	20,570,000
2012	N/A	N/A	2,000,00	2,380,000	185,000,000	220,150,000	8,000,000	6,000,000	5,000,000	19,000,000	22,610,000
2013	3,000,000	3,510,000	N/A	N/A	275,000,000	321,750,000	8,000,000	6,000,000	5,000,000	19,000,000	22,230,000
2014	5,000,000	5,750,000	N/A	N/A	224,000,000	257,600,000	8,000,000	6,000,000	4,000,000	18,000,000	20,700,000
2015	4,000,000	4,560,000	N/A	N/A	229,000,000	261,060,000	5,000,000	8,000,000	5,000,000	18,000,000	20,520,000
2016	3,000,000	3,390,000	1,000,000	1,130,000	253,000,000	285,890,000	9,000,000	8,000,000	5,000,000	22,000,000	24,860,000
2017	58,858	65,921	1,788,224	2,002,811	282,945,120	316,898,534	10,000,000	8,000,000	6,000,000	24,000,000	26,880,000
2018	150,048	162,052	1,930,850	2,085,318	227,387,381	245,578,371	10,000,000	9,189,334	8,230,000	27,419,334	29,612,881
2019	0	0	1,718,468	1,821,576	225,921,122	239,476,389	10,000,000	9,197,501	8,475,000	27,672,501	29,332,851
2020	365,670	383,954	1,818,833	1,909,774	218,211,069	229,121,622	13,000,000	10,221,570	9,070,000	32,291,570	33,906,149
2021	0	0	1,378,540	1,378,540	159,960,885	159,960,885	18,000,904	9,900,000	6,169,737	34,070,641	34,070,641
Total	15,574,576	17,821,926	14,634,915	16,338,020	2,699,426,177	3,051,995,803	113,000,904	93,508,405	71,944,737	278,454,046	310,292,521

Notes: Countermeasures Injury Compensation Program (CICP) and Vaccine Injury Compensation Program (VICP) are financed by taxes held in CCPF and VITF, respectively. FY: fiscal year; Comp: claims compensation; Admin.: administrative; DOJ: Department of Justice; HRSA: Health Resources and Services Administration; CFC: US Court of Federal Claims. The US Bureau of Labor Statistics Consumer Price Index Inflation Calculator in reference: (BLS n.d.) is used to convert dollar amounts in FY 2010–2020 into dollar amounts in FY 2021. *Source:* Data for FY 2010–2016 and FY 2017–2021 are retrieved from references: Office of Management and Budget, *Supra* note 61; *Supra* note 8; *Supra* note 35, respectively; the latter has more detailed information but limited time periods.

required by judicial law to explain the reasoning for its judgments.[50] Therefore, the Vaccine Court has a relatively higher degree of transparency. In contrast, the designated location of the CICP in DHHS is subject to administrative law.[51] Although the law requires the DHHS to publish CICP general policies (eg a new injury table) in the Federal Register, it does not require DHHS to explain and publish CICP individual cases, their executive adjudications, or their reasoning.

Second, because the judicial system follows case law tradition valuing precedents, VICP adjudicators are likely more inclined to make information publicly available.[52] In contrast, the administrative law governing DHHS executive actions on CICP claims lacks such a tradition, and the unavailability of precedents can shield DHHS from being questioned by petitioners. Therefore, DHHS executive adjudicators in CICP may have less incentive to improve transparency than do their judicial counterparts in VICP.

Third, DHHS regulations protect patient privacy under the Health Insurance Portability and Accountability Act,[53] which may make DHHS adjudicators more cautious about violating privacy and thus more reluctant to publish petitioner health information. Taken together, the CICP executive location is likely the main source of the program's lack of transparency.

V. COST-EFFECTIVENESS EFFICIENCY OF CICP

Cost-effectiveness efficiency refers to producing a good or service using the lowest-cost production method among all technically efficient methods.[54] Applying this definition to our study, both the CICP and VICP provide the same service to adjudicate vaccine injury claims, even though the CICP also receives non-vaccine injury claims. However, CICP does not have the lowest administrative costs[55] or the lowest processing time, compared with VICP, suggesting a lack of cost-effectiveness efficiency.

V.A. Administrative Costs

Of the $9.21 million spent by CCPF during FY 2017–2021, $8.64 million (94%) was spent on administrative costs, 15.03 times the $0.57 million (6%) spent on compensation (Table 3, Figure 1A).[56] In contrast, during the same period, the Vaccine Injury Compensation Trust Fund (VITF) as the funding source of VICP spent $1.26 billion, of which only $145.71 million (12%) was spent on administrative costs, leaving the

50 U.S. Court of Federal Claims, *Supra* note 38; Johnson et al., *Supra* note 32; U.S. Federal Rules of Civil Procedure (2020). "Rule 52. Findings and Conclusions by the Court; Judgment on Partial Findings (a) Findings and Conclusions. (1) In General. In an action tried on the facts without a jury or with an advisory jury, the court must find the facts specially and state its conclusions of law separately. The findings and conclusions may be stated on the record after the close of the evidence or may appear in an opinion or a memorandum of decision filed by the court."

51 *Supra* note 7.

52 Derry Ridgeway, *No Faults Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J Health Polit Policy Law 59 (1999).

53 Health Insurance Portability and Accountability Act of 1996, Pub.L. 104–191 (1996).

54 Jeremiah Hurley, *An Overview of the Normative Economics of the Health Sector*, in 1 Handbook of Health Economics, 1, 55–118 (Anthony Culyer, Joseph P. Newhouse eds., 2000).

55 See justification of using both proportion and amount of administrative costs in Section VII.A.

56 *Supra* note 8.

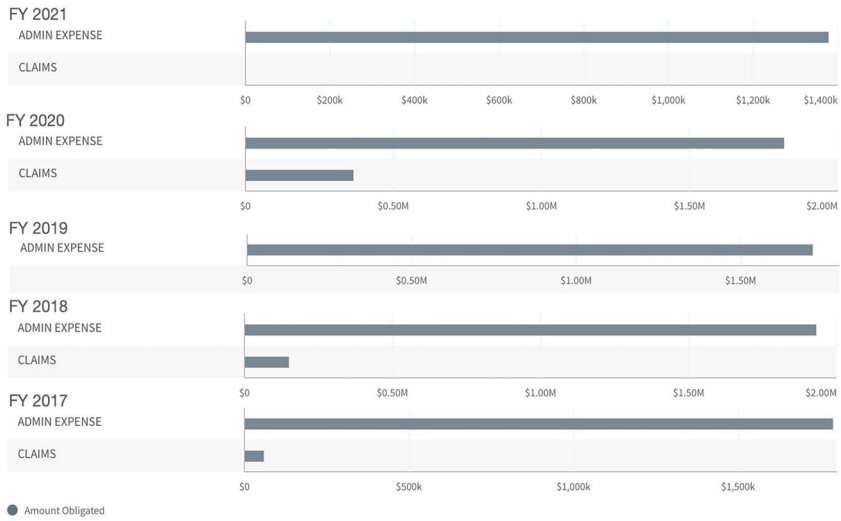

Figure 1A. Comparing Covered Countermeasures Process Fund (CCPF) and Vaccine Injury Compensation Trust Fund (VITF): spending categories FY 2017–2021 ($ USD). (A) CCPF *Source*: Data for FY 2017–2021 are retrieved from reference: *Supra* note 8. (B): VITF *Source*: Data for FY 2017–2021 are retrieved from reference: *Supra* note 35. (C): CCPF (CICP) Administrative Costs Breakdown *Source*: Data for FY 2017–2021 are retrieved from reference: *Supra* note 8.

majority $1.1 billion (88%) for compensation;[57] administrative costs included costs borne by the Claims Court, DHHS medical expert fees, and Department of Justice (DOJ) and petitioners' attorney fees incurred to adjudicate claims (Table 3, Figure 1B). Thus, the 94% proportion of CICP administrative costs was significantly higher than the corresponding 12% of VICP,[58] the 8–10% of some federal safety-net programs such as Medicaid,[59] and the 15% statutory limit on other federal programs such as Head Start.[60]

The amount of administrative costs on a per capita basis cannot be calculated due to inconsistent data between different federal government sources.[61] On a per adjudicated claim basis, during the past decade FY 2010–2021, the average administrative cost per adjudicated claim of CICP ($41,892) is about 1.7 times higher than that of VICP ($24,719); however, the average compensation paid per adjudicated claim of CICP ($45,697) is merely 18.8% of that of VICP ($243,129, Table 4). Recall that

57 U.S. Department of the Treasury, *Vaccine Injury Compensation Trust Fund Federal Account Profile*, https://www.usaspending.gov/federal_account/075-8175 (accessed Sep. 1, 2021).

58 *Supra* note 8; *Id.*

59 Robert Greenstein. *Romney's Charge That Most Federal Low-Income Spending Goes for 'Overhead' and 'Bureaucrats' Is False*. https://www.cbpp.org/research/romneys-charge-that-most-federal-low-income-spending-goes-for-overhead-and-bureaucrats-is (Accessed Dec. 20, 2021).

60 Early Childhood Learning & Knowledge Center, *Head Start Policy & Regulations*, https://eclkc.ohs.acf.hhs.gov/policy/45-cfr-chap-xiii/1303-5-limitations-development-administrative-costs (Accessed Dec. 20, 2021).

61 *Supra* note 8; *Supra* note 57; Office of Management and Budget, *Department of Health and Human Services Budget Appendix* https://www.govinfo.gov/app/collection/budget (accessed Aug. 2, 2021).

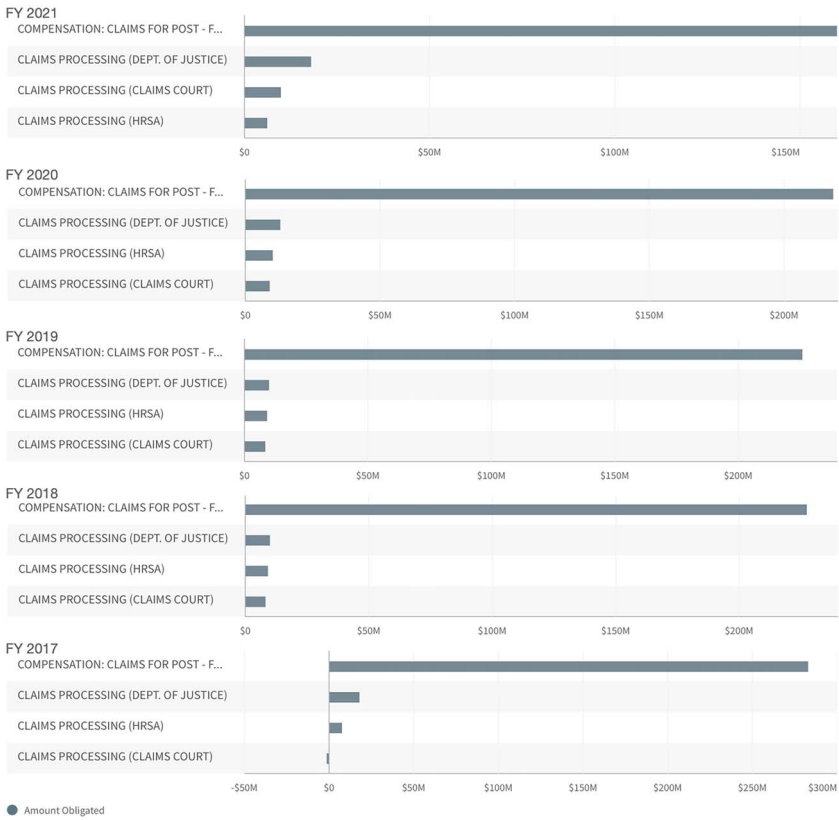

Figure 1B. Continued

CICP covers administrative costs of one agency DHHS-HRSA, whereas VICP covers administrative costs of three agencies—DHHS-HRSA, Claims Court, and DOJ. Thus, one can expect that the CICP administrative costs per claim would be lower, but quite the opposite, those costs are nearly double the VICP administrative costs per claim. Therefore, CICP's cost-effectiveness efficiency is questionable.

CICP pays permanent full-time annual salaries and benefits (Figure 1C) but becomes operational only during declared emergencies, only two of which have occurred in the past decade (H1N1 and COVID-19).[62] Given scarce fiscal resources and soaring public debt, is CICP worth such high administrative costs? We examine this question further in the following sections.

V.B. Time Costs

The economic worth of CICP further depends on how quickly CICP medical experts process claims compared with their non-emergency VICP counterparts, who are spe-

62 Most declared emergencies between 2009–2021 were related to natural disasters, such as storms and hurricanes, and opioid crises, and only three were related to pandemics, including H1N1, Zika, and COVID-19. However, no claim against Zika virus vaccines was filed in CICP. U.S. Department of Health and Human Services, *Public Health Emergency Declarations*, https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx (accessed Dec. 23, 2021)

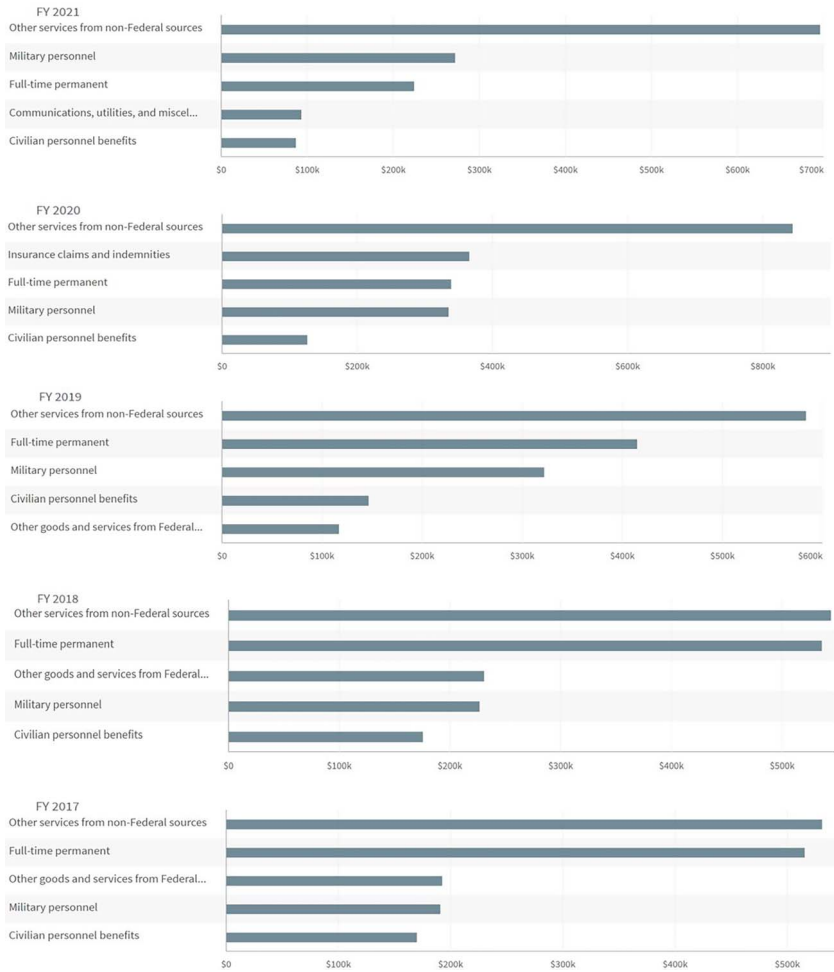

Figure 1C. Continued

cial masters and judges specialized in vaccine claims. However, the fact that CICP adjudicates claims against an emergent pandemic does not imply that it adjudicates these claims at an emergent speed. If the CICP medical experts can already serve as defendants or expert witnesses in VICP and do not process claims faster than their VICP counterparts, who function continuously, then CICP's economic value is debatable.

Unfortunately, due to the CICP transparency problem, we do not have any publicly available information about the target time limit or the actual time CICP takes to process a claim. In contrast, the VICP operates under statutory time limits of 240 and 420 days, respectively, for a special master opinion and a Claims Court judgment and makes the actual processing time publicly available.[63] Yet, the length of the VICP processing time was also questioned in the literature as well as in surveys among

63 Johnson et al, *Supra* note 32; *Supra* note 38.

Table 4. Comparing Covered Countermeasures Process Fund (CCPF) and VITF: Compensation and administrative costs per claim FY 2010–2021 (deflated 2021$ USD)

	CCPF(CICP)	**VITF(VICP)**
Total claims compensation	$17,821,926	$3,051,995,803
Total administrative costs	$16,338,020	$310,292,521
Total number of adjudicated claims	390	12,553
Total number of compensated claims	29	5842
Total number of dismissed claims	361	6711
Claims compensation per adjudicated claim	$45,697	$243,129
Administrative costs per adjudicated claim	$41,892	$24,719

Notes: Countermeasures Injury Compensation Program (CICP) and Vaccine Injury Compensation Program (VICP) are financed by taxes held in CCPF and VITF, respectively. *Source*: Data are prepared by authors using data from Table 3. Per adjudicated claim values are calculated using the total number of adjudicated claims as the denominator.

petitioners, petitioner attorneys, and the general public.[64] Nevertheless, statutory time limits, which have been lacking in CICP, make VICP more efficient than traditional courts.[65]

The time costs of the CICP to adjudicate COVID-19 claims are more uncertain. As of May 14, 2021, CICP has not made any decisions to compensate or deny any claims alleging injuries from COVID-19 countermeasures.[66] As of Aug. 2, 2021, CICP has denied two claims for "failing to meet the causality criteria."[67] These two claims relate either to COVID-19 non-vaccine countermeasures covered since Mar. 1, 2020, or to COVID-19 vaccines administered since Dec. 13, 2020, resulting in 7.5–17 months (225–510 days) processing time. This lengthy period is likely due to the fact that the CICP has not yet published a COVID-19 countermeasures injury table in the Federal Register for public comment or announced any specific compensation policy regarding these claims.[68] Recall that the injury table allows presumption of causation as long as a petitioner's symptoms meet the established causality criteria. Without such criteria, causality in each case must be established individually, which is time-consuming and inefficient. At the same time, other developed countries have announced such specific policies. For example, the U.K. added COVID-19 to its Vaccine Damage Payment program in December 2020, compensating individuals a lump sum amount of £120,000 ($165,000, Aug. 31, 2021 exchange rate) for > 60% disability due to COVID-19 vaccination.[69] The overall lack of timeliness and high administrative costs of CICP would indicate its lack of cost-effectiveness efficiency.

64 Johnson et al, *Supra* note 32. Government Accountability Office, *Vaccine Injury Compensation: Most Claims Took Multiple Years and Many Were Settled through Negotiation*, https://www.gao.gov/products/gao-15-142 (accessed Aug. 2, 2021); Johnson et al., *Supra* note 32.

65 Johnson et al, *Supra* note 32; Ridgeway, *Supra* note 52.

66 *Supra* note 13.

67 *Supra* note 5.

68 *Supra* note 11; *Supra* note 13.

69 Government of the United Kingdom, *Vaccine Damage Payment*, https://www.gov.uk/vaccine-damage-payment/eligibility (accessed Aug. 2, 2021).

V. C. Social Benefits

Alternative to the definition of cost-effectiveness efficiency,[70] we can also examine the efficiency of CICP using the conceptual framework of cost-effectiveness analysis: Given the two types of costs aforementioned, how effective was CICP in achieving at least two types of social benefits? First, are all entitled petitioners and their families compensated justly (ie satisfy causality criteria) and adequately to relieve the financial burdens associated with their injuries and productivity losses? Unfortunately, CICP data are not publicly available to answer this empirical question to date.

Second, as a public liability insurance mechanism, CICP can reduce the financial risk associated with the health risk related to COVID-19 vaccination; such risks without fair compensation have been a major source of concern among the general public, healthcare workers, and patients as revealed in vaccine hesitancy surveys[71] and have failed previous vaccination campaigns.[72] Therefore, just compensation can potentially incentivize unvaccinated individuals to vaccinate, which will then generate positive externalities and consequently a higher social welfare gain (eg healthier and more productive workforce, thus faster economic recovery).[73]

How large is the social benefit of CICP? In other words, how elastic is the demand for vaccination in response to changes in CICP compensation for vaccine injuries? Even if the magnitude of this elasticity is small, as long as it is economically and statistically significant, the CICP could be useful for vaccination policy-making. Therefore, this empirical question is worth evaluating. Unfortunately, CICP data are not publicly available to answer this question either. Taken together, there is evidence of the high administrative costs of CICP but less evidence about its time costs and social benefits compared with its VICP counterpart. Thus, data availability is urgently needed to evaluate CICP cost-effectiveness efficiency.

VI. ABILITY TO COMPENSATE

CICP's ability to compensate is also questionable. On the revenue side, Congress appropriated $27 billion in the Coronavirus Aid, Relief, and Economic Security Act and $3 billion in the American Rescue Plan to be spent on the "development, procurement, and distribution" of COVID-19 countermeasures; both amounts are seemingly abundant fiscal resources.[74] However, both appropriation laws did not specify whether

70 *Supra* note 54.

71 Ran D. Goldman, Tyler D. Yan, Michelle Seiler, et al., *Caregiver Willingness to Vaccinate their Children Against COVID-19: Cross Sectional Survey*, 38 Vaccine 7668 (2020); Jeanette B. Ruiz, Robert A. Bell, *Predictors of Intention to Vaccinate Against COVID-19: Results of a Nationwide Survey*, 39 Vaccine 1080 (2021); Ariana Remmel, *'It's a Minefield': COVID Vaccine Safety Poses Unique Communication Challenge*, 593 Nature 488 (2021); Michael Schwarzinger, Stephane Luchini, *Addressing COVID-19 Vaccine Hesitancy: Is Official Communication the Key?* 6 Lancet E353 (2021); Efthimios Parasidis, *Public Health and Institutional Vaccine Skepticism*, 41 J Health Polit Policy Law 1138 (2016).

72 Gostin (2006), *Supra* note 15; Institute of Medicine, The Smallpox Vaccination Program, Public Health in an Age of Terrorism (2005).

73 Daron Acemoglu, Simon Johnson, *Disease and Development: The Effect of Life Expectancy on Economic Growth*, 115 J Polit Econ 925 (2007); Jeroen Luyten & Philippe Beutels, *The Social Value of Vaccination Programs: Beyond Cost-Effectiveness*, 35 Health Aff 2 (2016); Pierrer-Yves Geoffard & Thomas Philipson, *Disease Eradication: Private versus Public Vaccination*, 87 Am Econ Rev 1 (1997).

74 Coronavirus Aid, Relief, and Economic Security Act of 2020, Pub. L. No. 116–136 (2020); American Rescue Plan Act of 2021, Pub. L. 117–2 (2021)

funds could be used for countermeasures injury compensation. Moreover, the Supplemental Appropriations Act of 2020 did specify that "funds appropriated under this heading in this Act may be transferred to, and merged with, the fund authorized by section 319F-4, the Covered Countermeasure Process Fund [CCPF]."[75] However, in FY2021 (October 2020–September 2021), besides a $5.79 million carryover from the previous year, the CCPF has received $0 from new appropriations and other budgetary resources,[76] has already spent $1.38 million on administrative costs,[77] and is left with a $4.41 million current balance. This underfunding problem signals a lower priority setting of CICP in the federal government agenda.

On the expense side, as of Aug. 2, 2021, the 1693 COVID-19 claims account for over 77% of the total CICP claims since 2010 (Table 2).[78] Among the non-COVID-19 claims, 29 of 493 (6%) were compensated with an average award of $209,520, totaling $6.07 million, according to the DHHS.[79] If current COVID-19 claims were to be compensated at the historical rate,[80] the program would face about $21.16 million in compensation outlays, a 245% increase, 4.8 times its current balance of $4.41 million. If administrative costs were added at the historical rate of 94%,[81] the program would face about $317.94 million in total outlays, a 5138% increase, 72.1 times its current balance, making CICP highly likely unable to compensate for current COVID-19 claims. Adding future claims and associated compensation and administrative costs will make this problem worse, if Congress does not appropriate funds promptly. Therefore, we raise concerns about CICP's ability to compensate for both current and future COVID-19 claims.

VII. DISCUSSION

VII. A. Why Were CICP Administrative Costs Unusually High?

Administrative costs, both in relative proportion and absolute amount, are crucial indicators to evaluate the efficiency of a government program.[82] CICP has unusually high administrative costs of 94%. In stark contrast, VICP has administrative costs of 12%; major federal safety-net programs (eg Medicaid) have 8–10%;[83] other federal programs (eg Head Start) have a 15% statutory limit of administrative costs.[84] Cutting high-cost low-output programs is a standard practice to improve the efficiency of allocating scarce financial resources in both public and private, and both health and

75 Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020, Pub. L. 116–123 (2020).

76 *Supra* note 8.

77 *Id.*

78 *Supra* note 5.

79 *Id.*

80 *Supra* note 8.

81 *Id.*

82 John L. Mikesell, Fiscal administration (2016); James D. Savage, *The Administrative Costs of Congressional Earmarking: The Case of the Office of Naval Research*, 69 Public Adm Rev 3 (2009); Marco Cangiano, Teresa Curristine, & Michel Lazare, Public Financial Management and Its Emerging Architecture (2013); Richard Allen, Salvatore Schiavo-Campo, & Thomas Columkill Garrity, Assessing and Reforming Public Financial Management (2004).

83 *Supra* note 59.

84 *Supra* note 60.

non-health sectors.[85] This supports our measurement of CICP efficiency using the proportion of its administrative costs in Section V.A.

To evaluate the comparative efficiency, comparing the absolute amount of administrative costs of a government program (eg CICP) to that of an alternative program (eg VICP), which provides similar services, is also valid and informative. One may argue that these two programs are too different to be compared. However, these two programs have already been compared in the literature and differ mainly with respect to timing, emergency and non-emergency, which is the very reason CICP was created in addition to VICP. In fact, from an economic perspective, both programs produce almost identical outputs, ie services that adjudicate and compensate vaccine injury claims. CICP also accepts claims from non-vaccine countermeasures, such as antiviral drugs and ventilators. Thus, there seem to be no fundamental differences between these two programs in terms of their outputs. Recall the economic definition of cost-effectiveness efficiency in Section V: If two methods (eg two government programs) produce the same output, but one (eg CICP) is much more costly per unit output than the other (eg VICP), then the more costly method (eg CICP) is inefficient in using scarce (eg fiscal) resources. And the relatively inefficient method needs to be either modified to be equivalently efficient or integrated into the more efficient method. This standard economic concept of efficiency and this standard public financial management practice[86] together are one of the bases on which we recommend the major reform and incremental changes in Sections VIII A and B.

Several counterarguments may be raised to justify the unusually high administrative costs of CICP. First, one may argue that high administrative costs are associated with a greater number of fraudulent claims in CICP. However, although we can neither reject nor support this hypothesis because of a lack of publicly available data, it is not likely given that filing fraudulent claims in CICP is likely more difficult and economically expensive than in VICP. Filing a CICP claim requires submitting an official request package, which includes all relevant personal and medical records of 1 year before the filing, and may also incur related medical and legal services and fees. Even if one invests all this time and money in a CICP fraudulent claim, after a long wait of 225–510 days, one may have only an average 6% chance to get compensated and, even so, may only receive an average $45,000. In comparison, VICP averages a 33–40% chance of compensation and nearly $250,000 per claim after no $>$ 240–420 wait days (see Section V). Thus, the economic return on fraudulent claims is much lower in CICP than in VICP, whose compensation is higher and wait time is shorter. Therefore, the

85 Mikesell (2016), *Supra* note 82; Gerald E. Caiden, *Administrative Reform*, in Handbook of Comparative and Development Public Administration 655–657 (Ali Farazmand ed, 2001); Wojciech Kpczuk, Justin Marion, Erich Muehlegger, & Joel Slemrod, *Do the Laws of Tax Incidence Hold? Point of Collection and the Pass-through of State Diesel Taxes*, National Bureau of Economic Research (2013); David M. Cutler, *Reducing Health Care Costs: Decreasing Administrative Spending*, U.S. Senate Committee on Health, Education, Labor, and Pensions (2018); Young Joo Park, *The Demise of the Overhead Myth: Administrative Capacity and Financial Sustainability in Nonprofit Nursing Homes*, 81 Public Adm Rev 3 (2020); Kevin Coyne, Shawn T. Coyne, & Edward J. Coyne Sr, *When You've Got to Cut Costs—Now*, Harv Bus Rev (2010); B. Charles Ames & James D. Hlavacek, *Vital Truths About Managing Your Costs*, Harv Bus Rev (1990); Kenneth E. Thorpe, *Inside the Black Box of Administrative Costs*, 11 Health Aff 2 (1992); *Supra* note 60.

86 Mikesell (2016), *Supra* note 82.

high administrative costs of CICP are less likely related to the number of fraudulent claims.

Second, one may also argue that CICP claims may be more complicated or require more medical expert testimonies than VICP claims. Again, this hypothesis remains untested due to data unavailability. To test this counterargument, we call for public disclosure in subsequent policy recommendations.

Third, given that CICP administrative costs and compensation costs are complements, one may argue that the administrative costs are proportionally high because the compensation is so low due to low statutory limits. However, the statutory limits are actually high. CICP has a $370,376 death cap and $379,000 lifetime cap for economic damages (ie lost employment income).[87] In contrast, VICP has only a $250,000 death cap and $250,000 cap for both economic and non-economic (ie pain and suffering) damages,[88] which is criticized for being too low by VICP petitioners.[89]

If high administrative costs are not related to high fraud, high complexity, or low compensation caps, then why are they unusually high? This is likely because nationwide public health emergencies are infrequent, and CICP implementation may incur waste. First, recall in Section V.A. that during the past decade FY 2010–2021, the average administrative cost per adjudicated claim of CICP ($41,892) is nearly double that of VICP ($24,719). To generate comparably low administrative costs per claim, CICP needs to have a doubled number of claims from a doubled number of declared emergencies. That is, four emergencies in 10 years, one emergency per 2.5 years in simple calculations. However, this would be unlikely. Because if an emergency is expected every 2.5 years, then it is predictable and is no longer uncertain. As a result, we would no longer need CICP to deal with uncertainty and instead rely on VICP. This brings the existence of CICP into question. Alternatively, if an emergency cannot be predicted, then the 2.5-year average frequency estimation is unlikely, especially given that influenza pandemics historically occur once every 25–30 years.[90] Therefore, it seems unlikely to have an inexpensive CICP, a compensation program only for public health emergencies.

Second, the CICP implementation may incur waste. To show this, we break down FY 2017–2021[91] CICP administrative costs into five main categories and calculate their average proportions of annual spending: 39% for other services from non-federal sources, 20% for full-time permanent annual salaries, 13% for military personnel, 8% for other goods and services from federal sources, and 7% for civilian personnel benefits (Figure 1C). Therefore, the top two cost categories, other services from non-federal sources and full-time permanent annual salaries, are responsible for nearly 60% of CICP administrative costs. According to the U.S. Office of Management and Budget,

87 Congressional Research Service, *Compensation Programs for Potential COVID-19 Vaccine Injuries*, https://crsreports.congress.gov/product/pdf/LSB/LSB10584 (accessed Aug. 2, 2021).

88 *Id.*

89 Government Accountability Office, Vaccine Injury Trust Fund: Revenue Exceeds Current Need for Paying Claims, https://www.gao.gov/assets/hehs-00-67.pdf (accessed Aug. 2, 2021).

90 Vaclav Smil, a Complete History of Pandemics (2020); Nita Madhav, Ben Oppenheim, Mark Gallivan, Prime Milembakani, Edward Rubin, & Nathan Wolfe, *Pandemics: Risks, Impacts, and Mitigation*, in Disease Control Priorities: Improving Health and Reducing Poverty (Dean T. Jamison, Hellan Gelband, Susan Horton, et al., eds, 2017).

91 *Supra* note 8. Breakdown data are only publicly available through FY 2017–2021.

the other services include purchases that are not otherwise classified, auditing of financial statements, typing and stenography, and tuition for the general education of employees.[92] However, in the absence of publicly available financial statements and audit reports, taxpayers simply do not know whether and how these unclassified purchases are justified. Therefore, we suggest a full public disclosure and auditing of CICP in our policy recommendations.

VII. B. Intended Designs or Unintended Consequences?

Historical documents of Congressional hearings on the PREP Act of 2005 show that Congress originally intended to create an injury compensation program prepared for public health and bioterrorist threats, which could occur at any time. Although Congress could not have foreseen that declared pandemics in need of countermeasure injury compensation were to occur only twice in the past decade (H1N1 and COVID-19),[93] it is also true that there have been near zero claims for most of those years. And yet, the CICP still had to pay for unclassified purchases and permanent full-time salaries and benefits every year, contributing to the unusually high administrative costs, and thus potential inefficiency in terms of cost-effectiveness. Had public health emergencies occurred more frequently, CICP would have been more efficient in terms of cost-effectiveness.

We could find no documentary evidence explaining the Congressional intent to locate CICP in the executive branch rather than in the judicial branch. It may have followed the way that other administrative compensation programs, such as the September 11th Victim Compensation Fund,[94] were located in the executive branch. Kenneth Feinberg, who helped design these other administrative programs, highlights that the general benefits of administrative procedures include efficiency, expedition, transparency, and due process.[95]

Yet, contrary to these assumptions, locating the CICP in DHHS has not produced a faster speed than the VICP, resulting in questionable efficiency. Moreover, Congress might not have considered the transparency problem of DHHS executive implementation governed by administrative law, which does not require public disclosure of adjudication of individual cases. Congress might also not have foreseen the DHHS potential conflict of interest, playing both roles as the defendant and the adjudicator, jeopardizing justice and fairness.

We also could not find any documentary evidence to explain the Congressional intent to preclude judicial review of DHHS executive agency actions on CICP claims. Feinberg highlights that typical administrative programs have due process.[96] Congress might have been trying to contain the total costs paid by the federal government by avoiding presumably lengthy court cases, prolonged judicial appeals, and high payouts. If Congress allowed additional judicial reviews, some cases would be decided at least twice, once by DHHS and once by courts, duplicating administrative costs and paying

92 Office of Management and Budget, *Supra* note 61.

93 *Supra* note 62.

94 Robert M. Ackerman, *The September 11th Victim Compensation Fund: An Effective Response to National Tragedy*, 10 Harv Negot L Rev 135 (2005).

95 Dixon et al, *Supra* note 9.

96 Dixon et al, *Supra* note 9.

possibly higher compensation. These total costs of DHHS executive adjudication and courts' judicial review could be even higher during potentially high-frequency and large-scale national emergencies, which would further exacerbate federal fiscal deficit and debt.

Despite Congress authorizing higher damage caps to CICP than VICP (see Section VII.A), Congress could not have foreseen that DHHS's decision on the entitlement of compensation would be as low as 6% and the amount of compensation would be $< \frac{1}{5}$ of the amount of VICP. Finally, no evidence shows that Congress considered that the lack of checks and balances for compensation decisions would be a consequence of disallowing judicial power, thus giving absolute executive power to DHHS.

Taken together, we acknowledge that Congress might have had good intentions and considered the tradeoffs when locating the CICP in the executive agency, DHHS, and prohibiting the judicial review of agency actions when designing CICP. It also might not have foreseen the unintended consequences when implementing CICP—DHHS conflict of interest and lack of checks and balances—which could jeopardize justice and subsequently weaken CICP performance. First, CICP lacks accountability because DHHS has a potential conflict of interest. Second, CICP lacks transparency because the administrative law that governs DHHS does not require public disclosure of the adjudication of individual cases. Third, CICP administrative costs are much higher in both proportion and amount than those of the VICP. Whereas CICP time costs do not seem to be lower than those of the VICP, and CICP societal benefits are less known due to public data unavailability; therefore, CICP cost-effectiveness efficiency is debatable. Fourth, CICP's ability to compensate is also questionable in the face of unprecedented demand from COVID-19 claims without additional Congressional appropriations to date.

VIII. POLICY RECOMMENDATIONS

To ensure just compensation and to serve injured petitioner and taxpayer interests, we call for reforming the general tax-funded CICP from an economic and public policy perspective. Our goal is not to assign blame to DHHS administrators in CICP, but to improve CICP performance and provide justice for the general public when such a program is most needed during COVID-19 and future public health emergencies.

VIII.A. Major Reform: Congress Relocates CICP from DHHS to Claims Court

To resolve the DHHS potential conflict of interest, which could jeopardize justice, we recommend Congress (1) relocate CICP from the DHHS to the Claims Court, (2) divide CICP claims into vaccine and non-vaccine claims, (3) merge the vaccine claims with the Vaccine Court within the Claims Court, and (4) maintain the non-vaccine claims as a separate program within the Claims Court.

This relocation will solve the DHHS potential conflict of interest, in which DHHS acts as both defendant and adjudicator of CICP claims, where less favorable decisions for petitioners would leave more funds for the agency. Thus, DHHS may have less incentive to seek just and adequate compensation for petitioners without judicial review. Therefore, relocating CICP from DHHS to Claims Court can eliminate the role

of DHHS as an adjudicator and add judicial power, thus resolving both fundamental problems.

As a third party, the Claims Court would not have a conflict of interest; its role is the adjudicator, whereas the DHHS's role is the defendant. But even if the Claims Court decision favors DHHS at the expense of petitioners, petitioners and their attorneys will have the chance to argue with DHHS and DOJ attorneys in the Claims Court as the first step, and then at the Appeals Court, which can help reduce the chances of unjust decisions. Concurrently, judicial power will be in place to balance the executive power, thus enhancing justice and accountability.

In addition, this relocation will improve CICP's other two performance indicators: transparency and efficiency. Specifically, this relocation will provide CICP petitioners and the general public with the following benefits of judicial adjudication: public disclosure of information, valuable precedents, identifiable independent adjudicators, explanation of reasoning, and statutory time limits, all of which will likely enhance CICP transparency and efficiency. This relocation to the Claims Court could also save significant administrative costs by avoiding duplicative infrastructure between the programs.[97] Merging CICP vaccine claims with the Vaccine Court, whose adjudicators are specialized in vaccine claims, will further reduce time costs and highly likely enhance efficiency.[98]

One may argue against this relocation, thus keeping CICP within DHHS, because the U.S. may face a relatively high risk of public health emergencies. Although the Congressional intent is to have a compensation program with better preparedness for emergencies, to the best of our knowledge, no other country seems to have the duplicative infrastructure to address such emergencies, and the literature criticizes this inconsistency in the American approach to vaccine injury compensation.[99] Moreover, in the past decade, the program has functioned only twice and not as well as designed, having been outperformed by its non-emergency counterpart, the Vaccine Court. Recall our earlier discussion that cutting inefficient programs is a standard practice in public financial management. Since DHHS medical experts can defend or serve as expert witnesses in the Claims Court, CICP emergent claims can be prioritized during emergencies in the Claims Court if needed, which uses existing non-emergency infrastructure efficiently without incurring duplicative costs.

One may also argue against the relocation because it could be expensive. However, this may not be the case because Vaccine Court adjudication is distinct from traditional civil litigation. Compensation under the Vaccine Court has been intended by Congress to be less litigious and more expeditious than compensation obtained through traditional tort litigation.[100] Similar to the CICP, the Vaccine Court reduces costs by using injury tables, lowering the requirement of strict proof of causation in traditional tort

97 Meyers (2011), *Supra* note 14; Congressional Research Service, Compensation Programs for Potential COVID-19 Vaccine Injuries, https://crsreports.congress.gov/product/pdf/LSB/LSB10584 (accessed Aug. 2, 2021).

98 Johnson et al, *Supra* note 32; Government Accountability Office, *Supra* note 64.

99 Mello (2008), *Supra* note 16.

100 Johnson et al, *Supra* note 32; Committee on Government Reform, *The Vaccine Injury Compensation Program: Addressing needs and improving practices,* https://www.congress.gov/congressional-report/106th-congress/house-report/977/1?s=1&r=9 (accessed Aug. 2, 2021).

litigations. Different from the CICP, the Vaccine Court contains costs by paying limited attorney fees,[101] eliminating contingency fees as in traditional tort litigations.

Therefore, relocating CICP to the Claims Court and further merging CICP vaccine claims into the Vaccine Court would be inexpensive. To show this, we have conducted a simulation study of proposed policies, one of which shifts existing COVID-19 claims in CICP from DHHS to the Claims Court.[102] The simulation exercise shows that given the Court's historical average compensation rate, compensation costs, and administrative costs per claim during FY 2010–2021, the existing 3158 COVID-19 claims as of Oct. 1, 2021 would cost $561.4 million in total outlays. This can be paid in full through FY 2021–2027 by using only the interest of $602.7 million earned on Treasury bills invested by the Court's funding source VITF. This way, passively paying for COVID-19 claims using the investment income of VITF in the subsequent 7 years would require $0 Congressional appropriations and $0 tax increases that would be challenging given a shrunken national income thus a shrunken tax base during and following a health crisis. Therefore, it will be economically and politically (taxwise) feasible to relocate CICP from DHHS to the Claims Court.

According to the literature, the political will to act relies largely on four factors: (1) a sufficient set of decision makers, (2) a common understanding among decision makers of a particular problem on the formal agenda, (3) a commitment by decision makers to support a resolution, and (4) a commonly perceived, potentially effective policy solution.[103] Applying this general framework to the particular relocation recommendation, we find the following.

First, there may be an insufficient number of decision makers, because the legislation (PREP Act of 2005) has excluded the judicial branch, and the executive branch, DHHS in particular, has no incentive to terminate its power to implement CICP. However, some legislators do generally support improving the welfare of vaccine injured petitioners. For example, House Bill 3655 (or Vaccine Injury Compensation Modernization Act of 2021) was introduced by the House Energy and Commerce Committee on June 1, 2021.[104] It proposes amendments to the NCVIA of 1986, such as increasing VICP compensation caps. Unfortunately, the Bill has stalled after being referred to the Subcommittee on Health, signaling an impasse.

Second, despite various problems highlighted in this paper, evidence of the efficiency of CICP is still thin due to the unavailability of public data, making it difficult for legislative and executive decision makers to reach a consensus on the nature of these problems. For example, the design problems and unintended consequences require solutions in further legislation; the implementation problems and performance weaknesses require solutions in further execution, which are less likely to be acknowledged by DHHS. Moreover, to date no civil lawsuit against CICP within DHHS has come before the judicial branch, which has been excluded from decision making by legislative design.

101 Johnson et al, *Supra* note 32.

102 Manuscript available from the authors upon request.

103 Lori Ann Post, Amber N. W. Raile, & Eric D. Raile, *Defining Political Will,* 38 Politics and Policy 4 (2010).

104 Vaccine Injury Compensation Modernization Act of 2021, HR 3655, 117th Congress. (2021).

Third, the remaining decision makers may not be committed to supporting major reform. Without significant pressure from various interest groups, Congress and DHHS may not be committed to finding a resolution for CICP. For example, the historically successful amendments to VICP relied on pressure from groups like parents of injured children and the Vaccine Injured Petitioners Bar Association.[105] This lack of public pressure might be because the general public is uninformed or ill-informed about CICP problems, let alone dissatisfied enough to urge Congressional reform. This lack of outreach to the general public is also an issue for VICP, which has been criticized for not promoting public awareness of the program and failing to adequately solicit public opinion about its processes.[106]

Fourth, because Congress is uninformed or ill-informed about the CICP's potential design flaws and implementation problems, it is less likely to act until confronted with more evidence, which paradoxically requires a willingness to collect and act in the first place. DHHS, acting in its own interest, may be inclined to keep and modify CICP, rather than transfer it to the Claims Court. Thus, both legislative and executive decision makers may not agree that this relocation reform could be a fundamental solution.

However, this lack of will may not be because CICP has already functioned well within DHHS but because people may not know the extent to which it has not functioned well. Recall that DHHS potential conflict of interest and lack of checks and balances are the fundamental problems that could jeopardize justice. Knowingly keeping CICP within DHHS, Congressional inaction may fail to uphold justice. Therefore, in addition to the expedient solution that Congress authorizes shifting COVID-19 claims in CICP from DHHS to the Claims Court temporarily,[107] we recommend the fundamental solution that Congress authorize the relocation permanently.

VIII.B. Incremental Change: Congress Permits Judicial Review of DHHS Executive Actions on CICP Claims

Alternative to the major reform, Congress may consider incremental changes that keep CICP within DHHS, adding judicial and legislative powers to balance DHHS executive power in CICP implementation. Congress may (1) permit judicial review of DHHS agency actions on CICP claims, (2) compel DHHS to publicly disclose the adjudication process and results of CICP claims, and (3) impose statutory time limits on DHHS to process CICP claims.[108] Yet, none of these will resolve the fundamental problem of DHHS potential conflict of interest.

First, Congress may amend the "judicial review" subsection of the PREP Act of 2005 to permit judicial review of disputed CICP claims even after the administrative reconsideration.[109] This would add checks and balances as a deterrent to DHHS adjudicators making unjust decisions or willful misconduct, thus improving accountability. However, permitting judicial review while keeping CICP within DHHS may be more costly than simply relocating it to the Claims Court. Given the significantly low CICP compensation rate (6%) and amount ($45,697 per claim), it is likely that many

105 Vaccine Injured Petitioners Bar Association, https://www.vipbar.org/ (Accessed Jan. 3, 2022).
106 Government Accountability Office, *Supra* note 64.
107 Meyers (2020), *Supra* note 14.
108 *Supra* note 64.
109 *Supra* note 7.

of the 94% uncompensated petitioners would seek judicial review, if permitted, for higher compensation under the higher caps (see Section VII.A), substantially increasing compensation costs. Even worse, it would also cause duplicative administrative costs for both DHHS and the Claims Court to adjudicate the same claims, further increasing the total costs. Thus, keeping CICP in DHHS while allowing judicial review is economically counterproductive. This incremental change would not fundamentally solve the problem and may cause more problems, making it a worse alternative to the relocation reform.

Second, Congress may compel DHHS to publicly disclose CICP decision-making process and results. This would improve transparency and provide data to evaluate CICP administrative and time costs and social benefits, allowing further assessment of CICP efficiency. Third, Congress may also impose time limits to reduce CICP time costs.[110] This has been done to VICP before, which was found to reduce average processing time efficiently.[111]

The political will for the incremental changes, especially judicial review, depends on the following four factors and thus is likely mixed. First, Courts would be relevant by adding a sufficient number of decision-makers to their legislative and executive counterparts in the relocation reform.

Second, do all three types of decision makers agree that forbidding judicial review is a problem? Courts may consider it a problem. Legislators' viewpoints may depend on whether they receive pressure from constituencies. However, DHHS administrators are less likely to recognize the lack of checks and balances as a problem. Administrative compensation program experts have criticized CICP within DHHS for its lack of due process.[112] Thus, non-DHHS administrators of other programs with the due process may consider CICP's lack of due process as a problem.

Third, are decision makers committed to supporting resolutions? Courts would be more likely to commit to restoring checks and balances for crucial decisions about national emergencies. Non-DHHS administrators are less likely to commit because it is irrelevant to their non-health area of expertise. DHHS administrators and legislators may wait for a political window when constituency groups intensively press for change.

Fourth, would all decision makers agree on judicial review as an effective solution to the lack of checks and balances? Courts may agree. Legislators may also agree if they receive intensive pressure from constituencies and are convinced by non-DHHS administrators and administrative compensation program experts that due process is necessary and effective.[113] However, DHHS administrators would likely disagree because CICP has already offered a one-time administrative reconsideration. They may also perceive judicial review as additional oversight, which would increase their workload. Taken together, the political will to permit judicial review of DHHS executive decisions on CICP claims is mixed.

110 Meyers (2011), *Supra* note 14.
111 Government Accountability Office, *Supra* note 64; Johnson et al (1998), *Supra* note 32.
112 Dixon et al, *Supra* note 9.
113 Dixon et al, *Supra* note 9.

VIII. C. Congress and DHHS Audit and Adjust Budgets for CICP

Independent of relocating CICP, we recommend that Congress and DHHS respectively request the Government Accountability Office (GAO) and Office of Inspector General (OIG) to conduct audits of the CICP (CCPF) and that Congress adjust the budgetary approval based on these audit reports in subsequent years. Both financial and performance audits are standard practices in public financial management.[114] Auditing CICP internally in the federal government or externally by third-party auditors will help keep DHHS accountable.

However, no CICP (CCPF) audit reports have been made available since its creation in 2005 because either audits have never been conducted or they have never been made public. Historically, only VICP (VITF) audit reports were available. The DHHS-OIG only provided a program review of VICP in 1992,[115] and the legislative auditor GAO conducted several performance audits of VICP from 1999 to 2014 and only one financial audit of VITF in 2000, which is > 20 years ago.[116] It is the COVID-19 pandemic that puts the spotlight on CICP (CCPF) and reveals their urgent need for audits.

Financial audits should investigate compliance:[117] Did CICP violate the requirements of appropriation laws? Were there uncompensated claims that satisfy causality criteria and compensated claims that fail to do so, and if so, how many? Were any CICP budgets misappropriated for purposes other than compensation and administrative costs directly associated with such compensation? Was there a significant risk to its ability to compensate current and future entitled claims, for example, from the rising COVID-19 variants?

Recall that the estimated costs to adjudicate and compensate the 3158 COVID-19 claims as of Oct. 1, 2021 would be $561.4 million (see Section VIII.A), whereas CICP has a current balance of $4.41 million with no new revenue in FY 2021 (see Section VI). Had financial audits been done, such a gap in the ability to compensate could have been prevented.

Performance audits should evaluate efficiency and effectiveness:[118] Were CICP administrative costs and time costs minimized for efficiency? How effective was CICP in achieving at least two types of aforementioned social benefits? First, are entitled petitioners and their families justly compensated, which adequately relieves the financial burden associated with their injuries and productivity losses? Second, how many members of society are incentivized to vaccinate for herd immunity, which would increase social welfare and accelerate economic recovery? Such elasticity of the demand

114 Miksell (2016), *Supra* note 82; Allen et al, *Supra* note 82; Cangiano et al, *Supra* note 82.

115 U.S. Department of Health and Human Services Office of Inspector General, The National Vaccine Injury Compensation Program: A Program Review, https://www.hhsoig.gov/oei/reports/oei-02-91-01460.pdf (accessed Aug. 2, 2021).

116 *Supra* note 64; Government Accountability Office, *Vaccine Injury Compensation Program Challenged to Settle Claims Quickly and Easily*, https://www.gao.gov/assets/hehs-00-8.pdf (accessed Aug. 2, 2021); Government Accountability Office, *Comparison of 'Fairness In Asbestos Injury Resolution Act of 2003 (FAIR Act),' and the existing National Vaccine Injury Compensation Program and Black Lung Benefits Program*, https://www.gao.gov/assets/b-301397.pdf (accessed Aug. 2, 2021); *Supra* note 90.

117 Mikesell (2016), *Supra* note 82.

118 *Id.*

for vaccination in response to the change in CICP compensation for vaccine injuries is an empirical question and requires public access to CICP data for further investigation.

Recall that CICP has an unusually high percentage of administrative costs at 94% (see Section V.A), nearly 10 times the 8–10% average of some federal safety-net programs and 6 times the 15% statutory limit of other such programs.[119] Recall also that to date CICP processes claims (225–510 days, see Section V.B) no faster than the Claims Court (240–420 days). Had performance audits been done, such questionable efficiency could have been identified and improved.

Therefore, we urge the Chair or ranking minority of one of the relevant committees (eg the House Ways and Means Committee, the House Energy and Commerce Committee)[120] to request GAO to audit CICP or hold oversight hearings as part of the DHHS appropriation process. Furthermore, Congress has assigned accountability for CICP spending and performance to the legal person (ie DHHS-HRSA), and DHHS has assigned that same accountability to the natural person (ie "Administrator of the HRSA").[121] However, an administrator may leave office. Therefore, we recommend DHHS additionally specify the duration of an HRSA Administrator's accountability to be the duration of that person's term of office. Therefore, based on audit reports, Congress could require DHHS to improve CICP performance, or withdraw DHHS authority over CICP if DHHS fails to do so, and penalize both legal and natural persons accountable for any possible misappropriation and abuse of CICP funds, a standard practice of public financial management.[122] Based on audit reports, Congress may also adjust budget approval for CICP to enhance its ability to compensate.

VIII. D. DHHS Publishes Causality Criteria for COVID-19 Countermeasures Injuries

Independent of relocating the CICP, efficiency and just adjudication need clearly established causality criteria. Thus, we recommend DHHS promptly publish the COVID-19 countermeasures injury table in the Federal Register to elicit public comment for a Final Rule. DHHS should also design a non-table compensation policy for such injuries, while the Final Rule continues to be developed. To implement, DHHS may need to immediately delegate the National Academy of Medicine (formerly the Institute of Medicine, IOM) to review existing epidemiological, clinical, and biological evidence of causality connecting injuries reported in claims to the use of COVID-19 countermeasures. DHHS and its associated scientific and regulatory agencies (eg FDA, Centers for Disease Control and Prevention, National Institutes of Health) may also prioritize funding epidemiological, clinical, and biological studies for such evidence of causality.

Causality plays a crucial role in the ability of CICP to adjudicate COVID-19 claims efficiently and justly. Without confirmed causality criteria, cases are decided on an ad hoc basis, which is also generally true for VICP. For example, IOM historically evaluated the since disproved link between certain vaccines[123] and autism.[124] Before

119 *Supra* note 59; *Supra* note 60.
120 *Supra* note 104.
121 *Supra* note 7.
122 Mikesell (2016), *Supra* note 82.
123 Measles, mumps, and rubella (MMR) vaccines and thimerosal-containing vaccines.
124 Institute of Medicine. Immunization Safety Review: Vaccines and Autism (2004).

this link was tested, the VICP had to hear each case, which was highly costly.[125] After the link was disproved, the VICP was able to immediately reject all claims of this kind,[126] saving significant time and administrative costs. Moreover, establishing the injury table as causality criteria can also facilitate financial audits that examine compliance by identifying how many claims that satisfy causality criteria were uncompensated, and conversely, how many compensated claims failed to meet the criteria.

However, nearly 2 years after declaring COVID-19 to be a public health emergency, such an injury table has yet to be available. It may be because DHHS has not started creating a table, for which no public information is found, or because two out of the three COVID-19 vaccines are mRNA-based, a new technology, thus having little existing evidence linking adverse events and vaccination. Historically, for the VICP injury table, the IOM took 3 years to review $>$ 200 epidemiological, clinical, and biological studies in the U.S. and abroad to firmly conclude no causal link between the aforementioned vaccines and autism.[127] For the CICP injury table, DHHS took $<$ 2.5 years after publishing the CICP Final Rule to publish the table for pandemic influenza H1N1.[128] Thus, we stress the importance of DHHS publishing such an injury table for COVID-19 countermeasures as early as possible.

IX. CONCLUSION

Vaccines and other countermeasures are utilized to combat the COVID-19 pandemic. Injuries from these countermeasures are required to be filed in the federal CICP during declared emergencies. The CICP is created and located in the DHHS, an executive agency, by the PREP Act of 2005 to adjudicate and compensate these injury claims. However, this article finds unintended consequences of the CICP design: First, the dual role of DHHS as both defendant and adjudicator leads to a potential conflict of interest. Second, not permitting judicial review of DHHS agency actions on CICP claims results in a lack of checks and balances. Both fundamental problems could jeopardize justice and further weaken CICP's four key performance indicators: lack of accountability and transparency, compromised efficiency, and questionable ability to compensate.

To ensure just compensation and to improve CICP performance for injured petitioners during COVID-19 and future public health emergencies, we need to resolve the fundamental problems rooted in CICP's location in and implementation by DHHS. Therefore, we recommend a major reform: Congress (1) relocates CICP from DHHS to the Claims Court, (2) merges its vaccine claims with the Vaccine Court, and (3) maintains its non-vaccine claims as a separate program in the Claims Court. Alternatively, Congress may keep CICP within DHHS while making incremental changes: Congress (1) permits judicial review of DHHS executive agency actions on CICP claims, (2) compels public disclosure, and (3) imposes statutory time limits on DHHS to process CICP claims. We further recommend that Congress and DHHS request GAO and OIG to audit CICP finances and performance, and adjust budget approval

125 Johnson et al (1998), *Supra* note 32.

126 U.S. Court of Federal Claims, Omnibus Autism Proceeding, https://www.uscfc.uscourts.gov/omnibus-autism-proceeding. (Accessed Jan. 3, 2021).

127 *Supra* note 125.

128 *Supra* note 7; *Supra* note 11.

for CICP based on audit reports. We finally recommend DHHS to promptly propose an injury table for COVID-19 claims.

This study is the first that contributes an economic perspective to the limited literature on CICP and provides unique economic data, despite DHHS's lack of disclosure of CICP information. We hope that this article serves as a stepping stone for multidisciplinary research in the fields of economics, law, political sciences, and public health to further examine this timely and important but highly multifaceted topic. We also hope our recommendations will benefit injured petitioners and taxpayers by improving CICP performance and justice. This reform depends on the willingness of DHHS to transfer CICP and the corresponding portion of its budget, but the ultimate success depends on the will of Congress to amend legislation that will allow the suggested modifications.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare that are relevant to the content of this article.